faegre drinker

faegredrinker.com

Susan M. Sharko
Partner
susan.sharko@faegredrinker.com
973-549-7350 direct

Faegre Drinker Biddle & Reath LLP
600 Campus Drive
Florham Park, New Jersey 07932
+1 973 549 7000 main
+1 973 360 9831 fax

April 13, 2020

VIA ECF

Honorable Freda L. Wolfson, Chief Judge
United States District Court- District of NJ
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street, Court Room 5E
Trenton, NJ 08608

Re: In re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation - MDL 2738

Andreas Saldivar v, Johnson & Johnson, et al.

Dear Chief Judge Wolfson:

I hope you, your staff and your loved ones are doing well during this challenging time for the State of New Jersey and the country.

I am writing in response to the PSC's letter dated April 9, 2020 regarding the recent state court deposition of Andreas Saldivar, in which he testified about the testing of Johnson's Baby Powder undertaken by AMA Analytical Services for the FDA in 2019.

Defendants agree with the PSC on one point: no further briefing or discovery is necessary or appropriate on these topics. As defendants explained to the Court in October 2019 when this issue first arose, the question before the Court is whether plaintiffs' experts' general causation opinions satisfy *Daubert*. The answer to that question does not turn in any way on Mr. Saldivar's testimony, which addresses procedures used by a government contractor to test Johnson's Baby Powder after plaintiffs submitted their expert reports in the MDL proceeding.

As explained in the attached document, which has been posted on the J&J website, www.factsabouttalc.com, J&J's own testing before the recall, and more than 150 tests conducted by two separate laboratories on the recalled lot, found no asbestos in Johnson's Baby Powder. But in any event, the identification of sub-trace amounts of asbestos in one sample of talcum powder, even if accurate, would not in any way affect the admissibility of plaintiffs' experts' general causation opinions. After all, it does not implicate the methodological flaws in plaintiffs' Bradford Hill analyses; it does not show that sub-trace amounts of asbestos can cause ovarian cancer; it says nothing about plaintiffs' highly speculative opinions regarding fibrous talc, heavy metals and fragrances; and it does not in any way endorse Dr. Longo's unreliable and highly subjective methods for purportedly identifying other forms of asbestos in the MDL samples.

Thank you for your consideration of this letter, and we look forward to your rulings on the pending motions.

Respectfully submitted,

/s/ Susan M. Sharko

Susan M. Sharko
FAEGRE DRINKER BIDDLE
& REATH LLP
600 Campus Drive
Florham Park, NJ 07932
Telephone: 973-549-7350
Facsimile: 973-360-9831
E-mail: susan.sharko@faegredrinker.com

Attorneys for Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. now known as Johnson & Johnson Consumer Inc.

cc: All Counsel of Record (via ECF)

Johnson & Johnson Consumer Inc.

Summary of Investigation

Johnson's Baby Powder (JBP) lot 22318RB was voluntarily recalled out of an abundance of caution after notification from the FDA that AMA Analytical Services, Inc. (AMA) testing reported chrysotile asbestos in test samples from an FDA-purchased bottle. The resulting investigation has determined that JBP does not contain chrysotile based on the totality of evidence.

- The talc deposit from the Jizhua Quarry Talc Mine in Guangxi, China does not geologically support the formation of chrysotile. In the 16 years that J&J Consumer Inc. (J&J Consumer) North America has sourced talc from this mine we have never found chrysotile asbestos in the talc.
- Our talc product is uniform via milling, heat treatment, and 15 blending steps in the manufacturing process that produce material uniformity. This uniformity allows us to confidently rely upon our test results being representative of the batch.
- There are numerous controls in place throughout the supply chain to prevent contamination. There is oversight of our talc from the mine through the milling and packaging process. Moreover, the absence of contamination in the Jizhua talc is confirmed by a robust quality control strategy that includes testing for asbestos in 5 places throughout the North American supply chain and 8 places in the global supply chain. We have never confirmed chrysotile asbestos through any of these analyses.
- All three Transmission Electron Microscopy (TEM) test methods used during this investigation to test the recalled lot (the methods used by AMA, RJ Lee & Buena Veritas Labs) are capable of detecting chrysotile at sub-trace levels if present. TEM is the highest precision test available for the detection of asbestos in powder.
- Two different third-party labs, RJ Lee and Buena Veritas Labs, conducted 155 tests using 4 different methods. No chrysotile was found in any of these 155 tests. Thirty-two (32) of these tests were conducted on samples collected from the FDA sample bottle from the recalled lot, including 6 tests on the AMA Lab blinded sample (2g), 3 of which were TEM tests, and 26 tests on the original FDA bottle (75g), including 20 TEM tests. Based upon the Fisher's Exact Test for statistical significance, 23 tests needed to be completed from the FDA sample bottle to achieve greater than a 99% confidence level that the bottle did not contain chrysotile. Accordingly, it is highly improbable that the 155 tests (of which 50 were TEM) would have shown no chrysotile while at the same time 2 of the 3 FDA samples tested by AMA would have given a positive result.
- It is readily apparent from review of the AMA report that AMA failed to (1) adhere to appropriate laboratory practice designed to prevent sample contamination, and (2) follow their own test method (NY ELAP 198.4 Modified Test Method) which requires identification methods as specified by ASTM 5756 & 40 CFR Part 763 Appendix A of Subpart E (AHERA).

Based on a totality of the evidence the most probable causes are lab contamination error and/or chrysotile misidentification by the analyst.

Event Description

On 16OCT2019, Johnson & Johnson Consumer Inc. (J&J Consumer) was notified by FDA of a positive result for chrysotile asbestos in FDA-purchased Johnson's Baby Powder (JBP) lot 22318RB as reported by AMA Analytical Services, Inc. (see Table 1 below). All prior J&J Consumer tests for the same lot are negative for the presence of asbestos.

Table 1: AMA Test Results provided by FDA

AMA Sample ID	% Chrysotile by TEM
308006-6	ND
308006-6A	<0.00001%
308006-6B	0.00002%

ND = Not Detected

Summary of Test Results

Initial Testing of Lot 22318RB Retains

Immediately upon notification of the positive test results obtained by AMA, J&J Consumer obtained retain samples of lot 22318RB and 4 raw material lots that were used during production of this finished goods lot from PTI. J&J Consumer commissioned RJ Lee Group (RJL) to perform asbestos testing by XRD, PLM and TEM, per RM-008967 Revision 7 on retain samples of lots listed in Table 2 below in order to determine if the positive results for chrysotile could be confirmed:

Table 2:

Lot Code	Content
H06158-D7	Milled Talc
H06228-D7	Milled Talc
H06148-D7	Milled Talc
H05168-D7	Milled Talc
22318RB	Baby Powder

Each sample was tested in triplicate for each method, for a total of 9 sample preparations for each lot tested. This testing was used as an initial confirmation of the J&J release results indicating that no asbestos was detected. RJ Lee's initial testing of one finished good sample and two raw material samples found the presence of chrysotile; however, after investigation, these results were invalidated due to laboratory contamination from a portable air conditioner used in an auxiliary room at RJ Lee. The final

report from RJL indicated that no asbestos was detected in any of the samples tested (see Table 3 below).

Table 3: Summary of Analytical Results

Lot Code	XRD			PLM			TEM			Analytical Sensitivity
	A	B	C	A	B	C	A	B	C	
H06148-D7	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.00000088%
H06158-D7	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.0000014%
H05168-D7	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.00000080%
H06228-D7	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.0000012%
22318RB	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.0000014%

ND = Not Detected

JBP Sampling at FDA

On 22OCT2019, trained J&J employees travelled to FDA Center for Food Safety and Applied Nutrition in College Park, MD in order to collect samples and document the collection of the samples.

During the visit J&J obtained two samples of JBP lot 22318RB which were sampled by the FDA: one approximately 2g aliquot of FDA's blinded sample, and one approximately 75g sample from the original 22oz FDA-sampled bottle.

3rd Party Laboratory Verification Testing

Bureau Veritas Certification Laboratory (BVL) Verification Testing Protocol was approved on 24OCT2019. The purpose of this protocol was for the Bureau Veritas Laboratory (BVL) to perform additional independent third-party verification of the RJL and AMA test results for the retain sample lots listed in Table 4 below.

Table 4: INV-106924-002 Test Samples

Lot Code	Content
H06158-D7	Raw Material (Milled Talc)
H06228-D7	Raw Material (Milled Talc)
H06148-D7	Raw Material (Milled Talc)
H05168-D7	Raw Material (Milled Talc)
22318RB	Finished Goods

Each sample was tested in triplicate by TEM and PLM according to both the RJL test methods and the BVL test methods, which are both comparable to the AMA method. This resulted in 12 sample preparations for each lot tested. Since BVL was not previously qualified by J&J, trained J&J employees were present to observe performance of all sample prep at BVL to ensure GMP requirements were met.

Results of all tests performed indicated that no asbestos was found in any of the samples using either the RJL or the BVL methods. It should be noted that in one sample of Raw Material lot H06228-D7 structures were observed with elemental chemistry that could be consistent with chrysotile and/or sepiolite using the modified ASTM D5756 (RJL) method. However, after exhaustive analyses by BVL, diffraction revealed no crystal structure or was not confirmed due to missing reflections. Sepiolite or an altered form of sepiolite is most likely the mineral structure present in the sample. Additionally, two particles consistent with the elemental chemistry of actinolite were initially observed; however, one particle did not meet the counting criteria and was omitted. Further verification on the second suspect structure by zone axis diffraction was performed and was not a match for actinolite. Lot H06228-D7 was re-prepared for a duplicate analysis and results indicated no asbestos fibers observed. Duplicate analysis was also performed on the original preparations for Lot H06228-D7, and no asbestos fibers were observed. The conclusion for Lot H06228-D7 was that upon completion of duplicate preparation and re-analysis no asbestos fibers were confirmed. These results provided further assurance that finished goods lot 22318RB and the raw material lots used to produce finished goods lot 22318RB were free of asbestos.

See Tables 5 and 6 below for a summary of results.

Table 5: Summary of Analytical Results for RJL Method:

Lot Number	PLM	TEM	Analytical Sensitivity
H06228-D7 Replicate 1	ND	ND	0.0000000256%
H06228-D7 Replicate 2	ND	ND	0.0000000180%
H06228-D7 Replicate 3	ND	ND	0.0000000202%
H06148-D7 Replicate 1	ND	ND	0.0000000255%
H06148-D7 Replicate 2	ND	ND	0.0000000183%
H06148-D7 Replicate 3	ND	ND	0.0000000271%
H05168-D7 Replicate 1	ND	ND	0.0000000186%
H05168-D7 Replicate 2	ND	ND	0.0000000193%
H05168-D7 Replicate 3	ND	ND	0.0000000337%
H06158-D7 Replicate 1	ND	ND	0.0000000274%
H06158-D7 Replicate 2	ND	ND	0.0000000197%
H06158-D7 Replicate 3	ND	ND	0.0000000197%
22318RB Replicate 1	ND	ND	0.0000000171%
22318RB Replicate 2	ND	ND	0.0000000217%
22318RB Replicate 3	ND	ND	0.0000000247%

ND = Not Detected

Table 6: Summary of Analytical Results for BVL Method:

Lot Number	PLM	TEM	Analytical Sensitivity
H06228-D7 Replicate 1	ND	ND	0.0000044%
H06228-D7 Replicate 2	ND	ND	0.0000034%
H06228-D7 Replicate 3	ND	ND	0.0000048%
H06148-D7 Replicate 1	ND	ND	0.0000045%
H06148-D7 Replicate 2	ND	ND	0.0000032%
H06148-D7 Replicate 3	ND	ND	0.0000032%
H05168-D7 Replicate 1	ND	ND	0.0000037%
H05168-D7 Replicate 2	ND	ND	0.0000041%
H05168-D7 Replicate 3	ND	ND	0.0000037%
H06158-D7 Replicate 1	ND	ND	0.0000048%
H06158-D7 Replicate 2	ND	ND	0.0000049%
H06158-D7 Replicate 3	ND	ND	0.0000047%
22318RB Replicate 1	ND	ND	0.0000037%
22318RB Replicate 2	ND	ND	0.0000048%
22318RB Replicate 3	ND	ND	0.0000044%

ND = Not Detected

Based on these corroborating test results from BVL, we can rule out that the RJ Lee analysts did not properly identify chrysotile and that RJ Lee results are a false negative.

Investigative Testing of FDA Sample

On 22OCT2019 J&J received two samples of Johnson's Baby Powder 22oz, Lot 22318RB from FDA:

1. Approximately 2g aliquot of FDA's blinded sample D58
2. Approximately 75g sample from the original 22oz bottle that was sampled by FDA for testing

J&J issued RJ Lee Group Investigative Testing Protocol, approved on 25OCT2019, to perform verification testing of the AMA results of the sample from the same D58 bottle. The 2g sample was tested for TEM and PLM in triplicate and the 75g sample was tested by TEM, XRD and PLM in triplicate using RJL test methods. Results of all tests performed indicated that no asbestos was found in any of the samples tested (see Table 7 below). This indicated that the samples retained by the FDA do not contain asbestos. This rules out potential root cause that the samples were contaminated during FDA sample handling and prior to shipment to AMA.

Table 7: Summary of Analytical Results for Protocol # INV-106924-003

Sample ID	XRD			PLM			TEM			Analytical Sensitivity
	1st	2nd	3rd	1st	2nd	3rd	1st	2nd	3rd	
D58 J&J Baby Powder Blinded sample Lot 22318RB	NA*	NA*	NA*	ND	ND	ND	ND	ND	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB	ND	ND	ND	ND	ND	ND	ND	ND	ND	0.0000014%

*NA – Analysis by XRD was not requested due to small sample size

ND = Not Detected

Investigative Testing of Additional Finished Good Lots

RJ Lee Group Product Retain Testing Protocol was approved for execution on 25OCT2019. The purpose of this protocol was to perform investigative testing to determine if asbestos was detected in retain samples of the three finished goods lots produced immediately before and the three finished goods lots produced immediately after lot 22318RB. The lots tested are listed in Table 8 below.

Table 8: INV-106924-004 Test Samples

Lot Number	Test Sample
21918R	Finished Goods
22118R	Finished Goods
22218R	Finished Goods
22518R	Finished Goods
22618R	Finished Goods
23018R	Finished Goods

A single sample of each lot was analyzed by TEM, XRD and PLM using RJL test methods. Results of all tests performed indicated that no asbestos was found in any samples tested. These results indicated that the finished goods lots produced immediately before and immediately after finished goods lot 22318RB do not contain asbestos and shows that the manufacturing process does not introduce

asbestos into JBP products (see Table 9 below). These results further rule out environmental/equipment contamination of JBP during production as a root cause.

Table 9: Summary of Analytical Results for lots manufactured before and after lot 22318RB

Lot Number	XRD	PLM	TEM	Analytical Sensitivity
21918RA	ND	ND	ND	0.0000014%
22118R	ND	ND	ND	0.0000014%
22218R	ND	ND	ND	0.0000014%
22518R	ND	ND	ND	0.0000016%
22618R	ND	ND	ND	0.0000011%
23018RA	ND	ND	ND	0.0000012%

ND = Not Detected

Additional Investigative Testing of FDA Sample from the 22oz Bottle

On 31OCT2019 an additional RJ Lee Group Investigational Testing Protocol was approved for execution. The testing requested in this protocol was used to evaluate the positive chrysotile results obtained by AMA Laboratory on 2 of 3 aliquots it tested from one bottle of Johnson's Baby Powder. Seventeen additional samples from the same bottle were tested to achieve a statistically significant population of results that can be evaluated through the investigation process. When added to the six replicates tested from the original 22oz bottle sampled by FDA in Protocol INV-106924-003, the additional seventeen replicates tested from the same bottle in this protocol satisfied a required sample size of 23 randomly-selected TEM samples from the same bottle. This sample size was determined using Fisher's Exact Test to demonstrate with more than 99% confidence that the powder in the original bottle does not contain asbestos. The samples were tested by TEM using the RJL test method. No asbestos was found in any samples, which confirms with more than 99% confidence that the original bottle sampled by FDA does not contain asbestos (see Table 10 below).

Based on these statistically significant results in conjunction with the material uniformity assessment, we can rule out the following potential root causes: Chrysotile is not found because it is not distributed uniformly in the sample/bottle, and: chrysotile contamination from packaging components.

Table 10: Summary of 17 Additional Replicates

Sample Description	TEM Result	Analytical Sensitivity
Original J&J Baby Powder Lot 22318RB Replicate 1	ND	0.0000016%
Original J&J Baby Powder Lot 22318RB Replicate 2	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 3	ND	0.0000016%
Original J&J Baby Powder Lot 22318RB Replicate 4	ND	0.0000012%
Original J&J Baby Powder Lot 22318RB Replicate 5	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 6	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 7	ND	0.0000016%
Original J&J Baby Powder Lot 22318RB Replicate 8	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 9	ND	0.0000012%
Original J&J Baby Powder Lot 22318RB Replicate 10	ND	0.0000016%
Original J&J Baby Powder Lot 22318RB Replicate 11	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 12	ND	0.0000012%
Original J&J Baby Powder Lot 22318RB Replicate 13	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 14	ND	0.0000014%
Original J&J Baby Powder Lot 22318RB Replicate 15	ND	0.0000012%
Original J&J Baby Powder Lot 22318RB Replicate 16	ND	0.00000097%
Original J&J Baby Powder Lot 22318RB Replicate 17	ND	0.0000012%

ND = Not Detected

Investigative Testing Summary

A total of 155 tests were performed by 2 different laboratories using 4 different test methods across multiple manufacturing lots. No chrysotile, or any other type of asbestos, was detected in any of the samples tested as part of this investigation. The data supports the absence of chrysotile in Johnson's Baby Powder. Additionally, apart from lab error, it is highly improbable[1] that AMA testing could detect chrysotile in 2 out of 3 samples and the results not be replicated in the RJ Lee testing of powder from the same uniformly mixed bottle.

Review of TEM Best Practices

The highest precision tool for detecting asbestos is TEM. TEM testing is a highly-specialized analysis that requires extensive training and qualification prior to execution. To assess the reported data and areas where lack of controls in the laboratory could lead to cross-contamination or analyst error, a literature search was performed concerning best practices for TEM analysis.

[1] Per Fishers Exact Test calculated for Bottle (required samples size of 23 for >99% confidence)

There are three distinct areas of importance when performing TEM; environmental design, mandatory auxiliary equipment and sample analysis (including analyst training and experience).

Assessment of the AMA execution of TEM testing against the information presented in the literature search could not be performed as these principles are not addressed in the AMA report. Therefore, the Investigation Team is unable to determine if AMA met these environmental, equipment, or sample analysis criteria during the analysis of JBP samples. Therefore, we cannot rule out potential root causes: (1) AMA method not executed properly: (2) Sample contamination during 10% reference sample prep: (3) Sample contamination during AMA sample handling and (4) Incorrect identification of structures.

Comparison of TEM Test Methodologies

To properly detect asbestos, test methods must have adequate sensitivity. To determine if the TEM test methods used by J&J Consumer and AMA could be considered comparable, a detailed test method comparison was performed by the Investigation Team. The comparison included the test methods performed by RJL and AMA and those required by J&J Consumer specifications and is detailed in Table 11 below.

Although currently effective at the time of the event, the J&J Consumer Test Method TM7024, was not currently in use for TEM testing. TM7024 is based on test methodology from McCrone Laboratories; that methodology was published in 1990 by Kremer & Millette. McCrone conducted TEM testing for J&J Consumer from 1971 until 1996. This method is no longer used for sample testing. J&J Consumer samples are sent to RJ Lee Group (RJL) and tested according to the RJL methods previously referenced in this document, which are modifications of ASTM D5756, an accepted industry standard for asbestos testing in talc by TEM. While TM7024 relies on the same fundamental principles of ASTM D5756, other contemporary methods, such as those currently in use at RJL, have improved analytical sensitivity and detection limits.

Table 11: Test Method Comparison

TM Aspect	RJ Lee TM.012.3/TM.033.1 (modified ASTM 5756)	AMA NY ELAP 198.4 (modified per AMA report)	Bureau Veritas KEN SOP-00008/4 KEN SOP-0002/6	J&J TM7024
Scope of Method	Olivine, Talc, Wollastonite, Carbonate	Organically Bound Bulk Samples	Bulk Materials (including talc) & tile samples	Powdered Talc
Sample Weight	5 mg	100 – 800 mg	200 mg for talc	10 – 30 mg
Ashing/Acid Wash	None	Yes: 480C for 12 hrs 0.5 mL Di water + 2–5 mL Conc. HCl	Yes: 480C for 5 hrs 1 mL Conc. HCl for 15 min	None
Dispersing Solvent	25 mL of DI Water	100 mL DI Water	100 mL DI Water	80 mL of 20 ppm methyl cellulose
Deposit onto TEM Grid	Filter	Filter	Filter	Drop Mount
Target Loading	5% – 20%	10 – 50% (per NY ELAP 198.4)	Target 20%	15% – 35%
TEM Magnification	Tier 1: 10,000X Tier 2: 20,000X	19,000X	15,000X -20,000X	Tier 1: 5,000X Tier 2: 20,000X
Grid Openings/Sample	Tier 1: 25 grids Tier 2: 10 grids Total: 35 grids	20 grids	100 grids	Tier 1: 14 grids Tier 2: 6 grids Total: 20 grids
Blank Control	Yes	Yes	Yes	Yes
Asbestos Reference Standard/Spike	No	Yes* (10% Standard) *Based on NY ELAP 198.4	No	No

TM Aspect	RJ Lee TM.012.3/TM.033.1 (modified ASTM 5756)	AMA NY ELAP 198.4 (modified per AMA report)	Bureau Veritas KEN SOP-00008/4 KEN SOP-0002/6	J&J TM7024
Sensitivity/LOD/LOQ	Sensitivity = use mass of smallest recordable fiber: L= 0.6 µm, W=0.10 µm using equation below $M(g) = \pi/4 \times L \times W^2 \times D \times 10^{-12}$ LOD: 10 – 30 ppb (0.000001% - 000003%) general asbestos 10 – 20 ppb (0.000001% – 0.000002%) Chrysotile	LOD = Observe 1 fiber LOQ= Observe 4 fibers Basis of LOD/LOQ Calculation Fiber = 0.5 µm X 0.04 µm $M(g) = \pi/4 \times L \times W^2 \times D \times 10^{-12}$ LOQ: 54 – 148.5 ppb (0.0000054% – 0.00001485%) Chrysotile LOD: 13 – 17 ppb (0.0000013% - 0000017%) Chrysotile	Use counting rules of one hypothetical structure L = 0.5 µm; aspect ratio 5:1 For confirmed observation of 1 – 3 asbestos fibers, based on Poisson statistics is considered indistinguishable from zero; still would be noted in report as observed Sensitivity Range: 5 – 50 ppb (0.0000005% - 0.000005%) If using ASTM D5756 approach for J&J INV study Smallest recordable fiber= L = 0.5 µm, W = 0.1 µm $M(g) = \pi/4 \times L \times W^2 \times D \times 10^{-12}$	Sensitivity = smallest recordable fiber L= 1.0 µm, W=0.075 µm Theoretical Sensitivity: 100 ppb (0.00001%) general asbestos Limit of Quantifiable Detection - Detection of 5 or more asbestiform minerals in one variety used to calculate using representative fiber size of: 3 µm x 0.2 µm x 0.06 µm Theoretical LQD = 600 ppb (0.00006%) general asbestos
Asbestiform Structure Confirmation	Morphology, SAED, EDX	Morphology, SAED, EDX	Morphology, SAED, EDX	Morphology, SAED, EDX

The detailed review of the RJL, AMA and J&J test methods indicated that the RJL and AMA methods produce similar sensitivities and incorporate technological advances that have been made since implementation of the TM7024 method. There are two main differences between RJL and AMA methods:

- AMA employs an ashing/acid wash step which is typically used for the analysis of bulk building materials and not pure inorganic powders
- RJL requires inspection of a total of 35 grids across two tiers of magnification, while AMA inspects 20 grids at a high magnification

These two differences would not be expected to impact the ability to detect chrysotile in a sample or result in differing test results.

Based on this assessment, the methods were determined to be similar in capability and sensitivities when executed correctly. We can rule out the following potential root causes: (1) AMA test method is more sensitive than RJ Lee testing method; (2) RJ Lee test method is not sensitive enough to identify chrysotile.

Expert Review of the AMA Lab Report and Test Results

Assessment of the AMA report identified a total of 18 areas of concern in sample preparation, reporting of results, test method considerations, sample handling and chain of custody, and miscellaneous other considerations. The following inconsistencies were identified:

Sample Preparation Issues:

1. The report indicates that an AMA chrysotile reference sample was prepared "alongside the customer samples", which may have introduced chrysotile into the test samples. Spiked reference samples are usually used for analyst or equipment qualification and should not be prepared next to a test sample. Additionally, 10% chrysotile is much higher than expected for trace asbestos evaluation of talc samples. According to NY ELAP 198.4 Section 8.2.3, at least 1 out of 100 samples must be a verified quantitative standard to demonstrate the analyst's precision and accuracy. However, in order to spike a 100mg sample (which is the minimum sample weight allowed in the method), 10mg of chrysotile would be needed. This mass of weighed chrysotile is several orders of magnitude greater than the trace levels reported in the test sample.
2. A review of other AMA reports posted on FDA's website indicated that reference samples for other test samples were spiked with only 1% chrysotile[2]. Introducing a 10% (or even a 1%) spike

[2] Reference the following reports from FDA.gov/cosmetics/cosmetic-ingredients/talc:

AMA Analytical Services, Inc. Summary of Asbestos and Talc Analysis – Beauty Plus – Timeless Beauty Palette, August 30, 2019

AMA Analytical Services, Inc. Summary of Asbestos and Talc Analysis – Beauty Plus – Matte Blush in Fuchsia, August 30, 2019

with chrysotile into the testing and performing alongside of the J&J sample may have led to contamination of the J&J sample.

Reporting of Results:

3. The % Acid Soluble and Gravimetric Loss from PLM % Acid Soluble results reported are conflicting between sample replicates, see Table 12 below.

Table 12: % Acid Soluble Results Reported by AMA

Sample	% Acid Soluble	Gravimetric Loss from PLM Prep % Acid Soluble (TEM)
6	6.7%	7.1%
6A	***19.5%***	8.5%
6B	***11.2%***	5.5%

The data show a significant discrepancy in acid soluble results between the two TEM replicates (6A and 6B) and the original sample (6), indicating that the replicates (6A and 6B) may not be representative of the original powder. Acid soluble results for the PLM samples are consistent with each other and consistent with the original sample; however, they are not consistent with the two anomalous TEM replicates (6A 19.5% and 8.5%; 6B 11.2% and 5.5%) or with the original sample (6).

Potential causes for the discrepant results for samples 6A and 6B could be sample mix-up or sample contamination during sample preparation.

4. The report documents the limit of detection (LOD) as one fiber and the limit of quantitation (LOQ) as 4 fibers; however, the result of one aliquot was reported to contain only two structures. No confirmatory testing was completed to determine the validity of these structures even though they are below the reported limit of quantitation that was determined by AMA. Both Analytical Methods referenced by AMA for the performance of TEM require confirmatory analysis; NY ELAP 198-4 in Section 5.1 and ASTM D5756 in Section 17.4. Results below the limit of quantitation should be thoroughly investigated to ascertain the validity of the observation, so it appears the procedure was not followed.
5. There are discrepancies in reported results documented within the report. For sample 308006-6A results are reported as follows:
   - % chrysotile = <0.00001%

AMA Analytical Services, Inc. Summary of Asbestos and Talc Analysis – Beauty Plus – Shimmer Bronzer in Caramel, August 30, 2019

AMA Analytical Services, Inc. Summary of Asbestos and Talc Analysis – Beauty Plus – Bronzer in Sunset, August 30, 2019

- % total = <0.00001%

However, Page 4 documents that the result for 308006-6A was <0.00002%. There is no explanation of the discrepancy. This causes concern around the accuracy of the data being reported.

6. On the Page 4 of the AMA Case Narrative, the wording was changed from "fiber" to "structure". There is no explanation of this change, and the report does not explain the difference in reporting, or if the distinction changes the test result.

Characterization of Structures:

7. The report identifies six total chrysotile structures in two of the three aliquots (308006-6A and -6B), but data is missing from each of the six particles that would allow a positive chrysotile identification:

- 308006-6A: Structure 1 (first particle):
  - There is no Energy Dispersive X-Ray Spectroscopy data included in the report, which is required to confirm the chemistry of the particle.
- 308006-6A: Structure 2 (second particle):
  - There is no Energy Dispersive X-Ray Spectroscopy data included in the report, which is required to confirm the chemistry of the particle.
  - There is no Selected Area Diffraction data included in the report, which is required to confirm the crystal structure of the particle.
  - This structure was measured to be 0.4 microns in length, which is below the minimum length of 0.5 microns and does not meet the counting criteria used in the analysis.
- 308006-6B: Structures 1a, 1b, and 1c (third, fourth and fifth particles):
  - In the analysis performed on 07SEP2019, Structure #1 was initially analyzed as 1 structure (identified as a "cluster" according to ASTM D5756/40 CFR part 763 appendix A subpart E (AHERA) counting protocols). On 11OCT2019 this 1 structure was updated to be 3 individual structures, counted separately. With this update, the structure count is above the quantification threshold; however, it is not clear why this was changed. While either may be considered correct according to the protocol used, it is atypical for an analyst to change the original count without outlining a valid reason or documenting that the initial count was in error.
  - Energy Dispersive X-Ray Spectroscopy (EDS) data is only included for one of these three structures, but there is no information as to which specific structure the data relates to. There is no Energy-Dispersive X-Ray Spectroscopy data included in the report for the other two particles, which is required to confirm the chemistry of the particles. According to the protocol used, the requirement of 4 structures were not confirmed by electron diffraction and EDS. Therefore, any additional structures past 4 cannot be assumed to be asbestos.
  - Selected Area Diffraction data is only included for one of these three structures. There is no Selected Area Diffraction data included in the report for the other two particles, which is required to confirm the crystal structure of the particles.

- 308006-6B: Structure 2 (sixth particle):
  - There is no Energy Dispersive X-Ray Spectroscopy data included in the report, which is required to confirm the chemistry of the particle.

Appropriate confirmation is required because, as clearly stated in ASTM D5756 Section 6.1, there are numerous other minerals (including sepiolite) "which are very similar to asbestos minerals and may interfere with the analysis by causing false positives to be recorded during the test."

8. Photos/Chemical Analyses presented in the report are not consistent with what they are reported to contain:

   - On Page 8, the diffraction pattern shown in Picture 1 is not confirmed by measurement of unique reflections to be consistent with chrysotile.

   The morphology, crystal structure and chemistry data of the structures reported do not confirm the identification of chrysotile. Two methods of identification of the structure were not followed as specified in ASTM D5756 and 40 CFR part 763 appendix A subpart E (AHERA).

9. The finding of mica is not consistent with the documented geological footprint of the Jizhua Quarry and indicates potential contamination of the sample.

Test Method Considerations:

10. The report documented that ELAP method 198.4 was the test method used for analysis. This method is generally used for the quantitation of higher levels of asbestos for organically bound materials, not for trace levels.
11. The weighing by AMA of the test samples sets forth a range of acceptable weights (0.1g to 0.8g) rather than setting the actual weight. Concentration of the test sample can have a significant impact on the test result. The report also does not define the volume of sample filtered, which also can impact the concentration. These differences can impact the method sensitivity between samples analyzed.

Sample Handling and Chain of Custody:

12. According to the report, the samples were submitted on 24JUL2019; however, they were not logged into the AMA database until 12AUG2019, and there is no documentation of where or how they were stored during this time period.
13. The report documents that sample vials were sealed with Scotch tape, which does not prevent sample contamination.
14. The AMA Chain of Custody form shows that a total of 15 samples (D53-D67) were logged in from FDA (the JBP sample was D58). There is no documentation to show if all samples were taken at the same time, or the environmental controls in place at the time of sampling. Additionally, there is no explanation of timing, sequence and environmental controls in place at AMA during sample preparation and testing. It is not documented if the other samples were tested alongside

sample D58. Testing of other products potentially containing asbestos could also lead to contamination of the JBP sample.

15. The AMA report contains no discussion on the environmental and sample handling controls that were used by AMA to test the sample, nor was a sample collection form available to document this. The American Society for Testing and Materials (ASTM) identifies contamination as a concern in asbestos analysis[3]. The report does not provide adequate assurance that the location of sampling was tested and confirmed to be asbestos free prior to handling the samples. This could lead to potential contamination of the JBP sample.

Timeline of Testing:

16. Inconsistencies were noted in the sample preparation and testing timeline at AMA, including the following:

- August 30 (Friday) – Primary JBP sample + 2 aliquots removed from the primary sample were prepared: samples 308006-6, 308006-6A, and 308006-6B.
- September 3 (Tuesday) – Prior to preparing or running either any blank samples or the reference sample containing 10% chrysotile, JBP sample 308006-6 was analyzed using Transmission Electron Microscopy (TEM). No asbestos was documented for this test sample.
- September 7 (Saturday) – JBP samples 308006-6A and -6B were analyzed by TEM and both tested positive, without an investigation to consider the potential of cross-contamination from the reference sample.
- September 13 (Friday) – the J&J testing was dated 9/13; however, sample preparation and testing began on 8/30.
- September 18 (Wednesday) – Analysis of three blank samples NB19-645, NB19-646, and NB19-647, air blank sample 54155, and the 10% chrysotile reference sample "RB"[4].

According to this timeline, sample 308006-6 was the only aliquot that was prepared and analyzed before preparation of the reference sample that was spiked with 10% chrysotile. The timeline also indicates blanks were not analyzed concurrently with or prior to the samples. Additionally, only 1 filter blank and 3 talc "controls" were analyzed. The blank and controls were reported to be negative; however, this small of a sampling is meaningless in background evaluation. According to ASTM D6620, 100 blanks performed with the sample parameters as the analysis are necessary to confirm that background contamination did not occur. Based on the timeline in the report there is the potential for cross-contamination of samples tested.

[3] ASTM 6620-19, Standard Practice for Asbestos Detection Limit Based on Counts, at 5.1.3(ii)
[4] The date of analysis for the 10% chrysotile reference sample "RB" is only mentioned on page 16 of the AMA Case Narrative, without any data to confirm its accuracy. The single page NOB Reference Sample Result sheet regarding to the 10% chrysotile reference sample "RB" is undated and includes no corresponding count sheets or other data.

Miscellaneous Discrepancies:

17. The AMA report documents that FDA requested a 4th sample preparation of vial D58 on 30SEP2019; however, AMA was instructed on 01OCT2019 not to test this sample. It is unclear why this analysis was discontinued, as preparation and analysis of a fourth aliquot separate from the preparation of the 10% chrysotile reference sample could provide further clarity on the likelihood of cross-contamination.
18. A modification to the method used stated, "All particles identified as tremolite were included with the counts/concentrations, regardless of size and aspect ratio." Although no tremolite particles were identified in this analysis rendering this statement irrelevant, this approach would mean that all tremolite particles would be counted and potentially listed as asbestos or summed with asbestos regardless of whether the particles were asbestos. The origin of this modification is not clear; however, it should be noted that not all tremolite amphibole particles are tremolite asbestos, especially in samples which are not building materials.

The assessment concluded that the AMA report did not provide a laboratory investigation into positive results, or adequate confirmation via two methods of identification of the structure as specified in ASTM D5756 and 40 CFR part 763 appendix A subpart E (AHERA) of the positive chrysotile result. Based on this information, it cannot be concluded that the test results are valid. The J&J Consumer investigation cannot rule out the following potential root causes: (1) AMA method not executed properly: (2) sample contamination during 10% reference sample prep; (3) incorrect identification of the particle: and (4) incorrect calculation of particle size.

Testing Conclusions

J&J Testing at RJ Lee Laboratory

- The test method comparison rules out potential root cause that the RJ Lee method is not sensitive enough to identify chrysotile.
- Investigation testing and the material uniformity assessment rule out potential root cause: Chrysotile not found because it was not distributed uniformly in the sample/bottle/lot.
- Investigational testing (performed by both RJ Lee and BVL), review of TEM best practices and RJ Lee test method assessment rule out the following potential root causes: RJ Lee inexperienced analysts do not properly identify chrysotile and RJ Lee lab results are a false negative.

Based on the above, and further strengthened by the material uniformity assessment this investigation has ruled out errors in J&J Testing at RJ Lee Laboratory as the root cause of the positive test for chrysotile in FDA sampled JBP lot 22318RB.

Testing at AMA Laboratory

- The test method comparison rules out potential root cause: AMA test method is more sensitive than RJ Lee testing methods.

- Lack of a laboratory investigation in the AMA Lab report means we cannot rule out the following potential root causes: (1) AMA method not executed properly: and (2) Sample contamination during 10% reference sample prep.
- Investigational testing of the FDA retained bottle rules out potential root cause 1d: contamination during FDA sample handling (prior to shipment to AMA).
- Investigation testing of the FDA sample aliquot rules out potential root cause 1f: product tested by AMA is not Johnson's Baby Powder.

Review of TEM best practices against the AMA Lab report cannot rule out potential root causes: (1) AMA method not executed properly: (2) Sample during AMA sample handling: (3) incorrect identification of particle and (4) incorrect calculation of particle size, leading to incorrect identification.

Conclusions

There is no impact to product or process as the result of this investigation end to end process, including mining, milling, packaging and testing of talc indicated that the J&J supply chain does not contain or introduce asbestos to talc products. Additionally, two different third-party labs conducted 155 tests using 4 different methods. No chrysotile was found in any of these 155 tests. Thirty-two (32) of these tests were conducted on samples collected from the FDA sample bottle from the recalled lot, including 6 tests on the AMA Lab blinded sample (2g), 3 of which were TEM tests, and 26 tests on the original FDA bottle (75g), including 20 TEM tests. Based upon the Fisher's Exact Test for statistical significance, 23 tests needed to be completed from the FDA sample bottle to achieve greater than a 99% confidence level that the bottle did not contain chrysotile. Accordingly, it is highly improbable that the 155 tests (of which 50 were TEM) would have shown no chrysotile while at the same time 2 of the 3 FDA samples tested by AMA would have given a positive result.

It is readily apparent from review of the AMA report that AMA failed to (1) adhere to appropriate laboratory practice designed to prevent sample contamination, and (2) follow their own test method (NY ELAP 198.4 Modified Test Method) which requires identification methods as specified by ASTM 5756 & 40 CFR Part 763 Appendix A of Subpart E (AHERA).

Finally, a Health Hazard Evaluation (HHE) determined that even if the values originally reported by FDA/AMA were to be accurate, the use of the product would not likely result in adverse health consequences.

Based upon the facts of this investigation, J&J Consumer stands behind the original release results of the product. However, despite the conclusions of the investigation and the tests showing no asbestos in the bottle or lot, the previously announced recall of Lot 22318RB of Johnson's Baby Powder, stays in effect. The recall was made out of an abundance of caution and before an investigation could be conducted, and, once initiated, it is not feasible to halt the recall.